CLAIMS

WE CLAIM:

1. A controlled release therapeutic composition comprising about 50-60% of an active agent, about 5-15% of a structural polymer carrier and about 15-40% of a solubilizing surfactant adapted to release the active agent over a prolonged period of time.

2. A controlled release therapeutic composition comprising topiramate, a structural polymer carrier and a solubilizing surfactant adapted to release the topiramate over a prolonged period of time.

3. The composition of Claim 2 wherein the dose of topiramate is between about 10mg and 750 mg.

4. The composition of Claim 2 wherein the dose of topiramate is between about 10 mg and about 250 mg.

5. The composition of Claim 2 wherein the dose of topiramate is between about 25 mg and about 400 mg.

6. The composition of Claim 2 wherein the dose of topiramate is between about 50% and about 55% of the composition.

7. The composition of Claim 2 wherein the amount of structural polymer is between about 5% and about 50% by weight of the composition.

8. The composition of Claim 2 wherein the amount of structural polymer is between about 5% and about 15% by weight of the composition.

9. The composition of Claim 2 wherein the structural polymer is polyethylene oxide of about 100,000 to about 200,000 molecular weight.

10. The composition of Claim 2 wherein the solubilizing surfactant is selected from the group consisting of polyoxyl 40 stearate, polyoxyl 50 stearate, poloxamers, and a:b:a triblock copolymers of ethylene oxide:propylene oxide:ethylene oxide.

11. The composition of Claim 2 wherein the amount of solubilizing surfactant is between about 5% and about 50% by weight of the composition.

12. The composition of Claim 2 wherein the amount of solubilizing surfactant is between about 5% and about 40% by weight of the composition.

13. The composition of Claim 2 wherein the amount of solubilizing surfactant is about 30%, the amount of structural polymer is about 11.5% and the amount of topiramate is about 55% by weight of the composition.

14. A controlled release therapeutic composition comprising topiramate, a structural polymer and a solubilizing surfactant adapted to increase the solubility of the topiramate.

15. A dosage form for controlled release of a therapeutic composition comprising topiramate, a structural polymer and a solubilizing surfactant adapted to release topiramate over a prolonged period of time.

16. The dosage form of Claim 15 wherein the dosage form is a matrix system.

17. The dosage form of Claim 15 wherein the dosage form is an osmotic system.

18. The dosage form of Claim 15 wherein the dosage form is adapted to be administered once a day.

19. The dosage form of Claim 15, which is adapted to release a high dose of topiramate.

20. The dosage form of Claim 19 wherein the high dose of topiramate is about 50% to about 60% by weight of the therapeutic composition.

21. The dosage form of Claim 19 wherein the high dose of the topiramate is about 30% to about 40% by weight of the dosage form.

22. A controlled release oral dosage form for once-a-day administration of topiramate comprising:

(a) A core which comprises:

i. Topiramate;

ii. a structural polymer;

iii. a solubilizing surfactant;

(b) a semipermeable membrane at least partially surrounding the core; and

(c) an exit orifice through the semipermeable membrane which communicates with the core so as to allow release of the topiramate to the environment;

wherein the dosage form releases the topiramate over a prolonged period of time.

23. The controlled release oral dosage form of Claim 22 adapted to release the topiramate at a substantially zero order release rate.

24. The controlled release oral dosage form of Claim 22 adapted to release the topiramate at a substantially ascending release rate.

25. A method for delivering high doses of topiramate comprising orally administering the dosage form of Claim 22 to a subject.

26. A method for enhancing the bioavailability of topiramate comprising orally administering the dosage form of Claim 22 to a subject.

27. The controlled release oral dosage form of Claim 22 wherein the topiramate is about 55%, the structural polymer is about 11.5%, and the solubilizing surfactant is about 30% of the core.

28. A controlled release oral dosage form for once-a-day administration of topiramate comprising:

(a) A core which comprises:

i. Topiramate;

ii. polyvinylpyrrolidone; and

iii. no solubilizing surfactant;

(b) a semipermeable membrane at least partially surrounding the core; and

(c) an exit orifice through the semipermeable membrane which communicates with the core so as to allow release of the topiramate to the environment;

wherein the dosage form releases the topiramate over a prolonged period of time.

29. A method for treating a condition responsive to topiramate comprising orally administering a capsule shaped tablet core dosage form containing topiramate, a solubilizing surfactant and a pharmaceutically acceptable structural polymer carrier wherein the dosage form releases the topiramate at a substantially ascending release rate for a prolonged period of time.

30. A method for treating a condition responsive to topiramate comprising orally administering a capsule shaped tablet core dosage form containing about 50-60% topiramate, about 5-15% of a structural polymer carrier and about 15-40% of a solubilizing surfactant wherein the dosage form

releases the topiramate at a substantially ascending release rate for a prolonged period of time.

31. A method for administering an active agent to a subject comprising:

Administering a dosage from to the subject wherein the dosage form comprises:

(a) a capsule shaped tablet core comprising a plurality of layers wherein a composition containing about 50-60% of an active agent, about 5-15% of a structural polymer carrier and about 15-40% of a solubilizing surfactant is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane at least partially surrounding the capsule shaped tablet core to form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the semipermeable membrane into the compartment; and

(c) an orifice formed through the semipermeable membrane and into the capsule shaped tablet core to permit the active agent to be released from within the compartment into the external fluid environment;

wherein the dosage form releases the active agent at a substantially ascending release rate for a prolonged period of time.

32. The method according to Claim 31 wherein the active agent is topiramate.

33. The method according to Claim 32, wherein the capsule shaped tablet core comprises two layers and the topiramate is contained within a first layer and the fluid-expandable polymer is contained within a second layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

34. The method according to Claim 32, wherein the capsule shaped tablet core comprises three layers and a portion of the topiramate is contained

within a first layer and the remaining portion of the topiramate is contained within a second layer, wherein the portion of topiramate contained within the first layer is less than the portion of topiramate contained within the second layer, and wherein the fluid-expandable polymer is contained within a third layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

35. The method according to Claim 34, wherein the proportion of topiramate contained within the first layer to the topiramate contained within the second layer is within the range of about 1.0:2.0 to about 1.0:1.2.

36. The method according to Claim 34, wherein the proportion of topiramate contained within the first layer to the topiramate contained within the second layer is within the range of about 1.0:1.5 to about 1.0:1.2.

37. The method according to Claim 34, wherein the proportion of topiramate contained within the layers to the solubilizing surfactant is within the range of about 0.5:1.0 to about 2.0:1.0.

38. A method for delivering an active agent, the method comprising orally administering a capsule shaped tablet dosage form containing a composition having about 50-60% of an active agent, about 5-15% of a structural polymer carrier and about 15-40% of a solubilizing surfactant wherein the dosage form releases the active agent from the dosage form at a substantially ascending release rate for a prolonged period of time.

39. The method of Claim 38 wherein the active agent is topiramate.

40. The method according to Claim 39, wherein the dosage form comprises:

(a) a capsule shaped tablet core containing a plurality of layers wherein topiramate is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane surrounding the capsule shaped tablet core to form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the semipermeable membrane into the compartment; and

(c) an orifice formed through the semipermeable membrane and into the capsule shaped tablet core to permit topiramate to be released from the compartment into the external fluid environment.

41. The method according to Claim 40, wherein the capsule shaped tablet core comprises two layers and the topiramate is contained within a first layer and the fluid-expandable polymer is contained within a second layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

42. The method according to Claim 40, wherein the capsule shaped tablet core comprises three layers and a portion of the topiramate is contained within a first layer and the remaining portion of the topiramate is contained within a second layer, wherein the portion of topiramate contained within the first layer is less than the portion of topiramate contained within the second layer, and wherein the fluid-expandable polymer is contained within a third layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

43. The method according to Claim 42, wherein the proportion of topiramate contained within the first layer to the topiramate contained within the second layer is within the range of about 1.0:2.0 to about 1.0:1.2.

44. The method according to Claim 42, wherein the proportion of topiramate contained within the first layer to the topiramate contained within the second layer is within the range of about 1.0:1.5 to about 1.0:1.2.

45. The method according to Claim 42, wherein the proportion of topiramate contained within the layers to the solubilizing surfactant is within the range of about 0.5:1.0 to about 2.0:1.0.

46. A capsule shaped tablet dosage form containing a composition having about 50-60% of an active agent, about 5-15% of a structural polymer carrier and about 15-40% of a solubilizing surfactant wherein the dosage form, following oral administration to a subject, releases the active agent from the dosage form at a substantially ascending release rate for a prolonged period of time.

47. The dosage form of Claim 46 wherein the active agent is topiramate.

48. The dosage form according to Claim 47 comprising:

(a) a capsule shaped tablet core containing a plurality of layers wherein the topiramate is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane surrounding the capsule shaped tablet core to form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the semipermeable membrane into the compartment; and

(c) an orifice formed through the semipermeable membrane and into the capsule shaped tablet core to permit topiramate to be released from within the compartment into the external fluid environment.

49. The dosage form according to Claim 48, wherein the capsule shaped tablet core comprises two layers and the topiramate is contained within a first layer and the fluid-expandable polymer is contained within a second layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

50. The dosage form according to Claim 48, wherein the capsule shaped tablet core comprises three layers and a portion of the topiramate is contained within a first layer and the remaining portion of the topiramate is contained within a second layer, wherein the portion of topiramate contained within the first layer is less than the portion of topiramate contained within the second layer, and wherein the fluid-expandable polymer is contained within a third layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

51. The dosage form according to Claim 50, wherein the proportion of topiramate contained within the first layer to the topiramate contained within the second layer is within the range of about 1.0:2.0 to about 1.0:1.2.

52. The dosage form according to Claim 50, wherein the proportion of topiramate contained within the first layer to the topiramate contained within the second layer is within the range of about 1.0:1.5 to about 1.0:1.2.

53. The dosage form according to Claim 50, wherein the proportion of topiramate contained within the layers to the solubilizing surfactant is within the range of about 0.5:1.0 to about 2.0:1.0.